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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,583	02/08/2002	Andrew William Heath	2257-1-002	2810

23565 7590 10/06/2004

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,583	HEATH, ANDREW WILLIAM	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/8/02.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 2/8/02, is acknowledged.
Claims 3-6, 8, 10, 12, 13, 15 and 18 have been amended.
Claims 26-30 have been added.

Claims 1-30 are pending.

The Marked Up Copy of the Claims of 7/8/03 are the claims restricted herein.

Applicant should carefully review the recitation of the claims as the instant claims are replete with ambiguity and insufficient / improper antecedent basis (e.g. see claims 13-19 and 27).

2. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods and products. As disclosed on page 5 of the instant specification, the method and products rely upon "adjuvants" encompassing anti-CD28 antibodies, B7.1 or B7.2 which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims. Further, it is noted that page 5, paragraph 6 of the specification discloses "an agent that due to its biochemical characteristics has an affinity for CD28. If applicant intends to amend the claims to recite additional "adjuvants" then such limitations would be subject to further restriction.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, 14 and 28-30, vaccines adapted to stimulate T cells as it comprises anti-CD28 as an adjuvant, classified in Class 424, subclass 184.1.

II. Claims 1-6, 8, 10, 11, 14 and 30, vaccines adapted to stimulate T cells as it comprises B7.1 as an adjuvant, classified in Class 424, subclass 184.1.

III. Claims 1-6, 8, 10, 11, 14 and 30 , vaccines adapted to stimulate T cells as it comprises B7.2 as an adjuvant, classified in Class 424, subclass 184.1.

IV. Claims 12-13, 20-22 drawn to methods of making vaccines adapted to stimulate T cells as it comprises anti-CD28 as an adjuvant via CD28, classified in Class 435, subclass 69.7.

V. Claims 12-13, 20-22 drawn to methods of making vaccines adapted to stimulate T cells as it comprises B7.1 as an adjuvant classified in Class 435, subclass 69.7.

VI. Claims 12-13, 20-22 drawn to methods of making vaccines adapted to stimulate T cells as it comprises B7.2 as an adjuvant, classified in Class 435, subclass 69.7.

VII. Claim 15, 23-24, drawn to a system, (e.g. a cell) that secretes antigen and adjuvant as it comprises anti-CD28 as an adjuvant, classified in Class 435, subclass 71.1, 326.

Applicant is invited to amend the claims and clearly define the scope and/or the metes and bounds of a "system".

VIII. Claim 15, 23-24, drawn to a system, (e.g. a cell) that secretes antigen and adjuvant as it comprises B7.1 as an adjuvant, classified in Class 435, subclass 71.1, 326.

IX. Claim 15, 23-24, drawn to a system, (e.g. a cell) that secretes antigen and adjuvant as it comprises B7.2 as an adjuvant, classified in Class 435, subclass 71.1, 326.

X. Claims 16- 17, 19, drawn to an adjuvant as it reads on anti-CD28 antibody, classified in Class 424, subclass 130.1,

XI. Claims 16, drawn to an adjuvant as it reads on B7.1, classified in Class 424, subclass 192.1,

XII. Claims 16, drawn to an adjuvant as it reads on B7.2, classified in Class 424, subclass 193.1,

XIII. Claim 18, drawn to a DNA encoding an antigen, classified in Class 536, subclass 23.1.

XIV. Claim 26, 25 and 27 ?, drawn to a DNA encoding an adjuvant as it encodes anti-CD28 antibody as an adjuvant, classified in Class 536, subclass 23.1

Given the insufficient antecedent basis for "encoding the recombinant fusion protein of claim 7", it is unclear whether claim 27 belongs in this Group.

XV. Claim 26, 25, and 27 ?, drawn to a DNA encoding an adjuvant as it encodes B7.1 as an adjuvant, classified in Class 536, subclass 23.1

Given the insufficient antecedent basis for "encoding the recombinant fusion protein of claim 7", it is unclear whether claim 27 belongs in this Group.

XVI. Claim 26 ,25 and 27 ?, drawn to a DNA encoding an adjuvant as it encodes B7.2 as an adjuvant, classified in Class 536, subclass 23.1

Given the insufficient antecedent basis for "encoding the recombinant fusion protein of claim 7", it is unclear whether claim 27 belongs in this Group.

XVII. Claim 25, drawn to a DNA encoding both an antigen and an adjuvant as it comprises anti-CD28 antibody as an adjuvant, classified in Class 536, subclass 23.4.

XVIII. Claim 25, drawn to a DNA encoding both an antigen and an adjuvant as it comprises B7.1 as an adjuvant, classified in Class 536, subclass 23.4.

XIX. Claim 25, drawn to a DNA encoding both an antigen and an adjuvant as it comprises B7.2 as an adjuvant, classified in Class 536, subclass 23.4.

4. Inventions I – III, VII-XIX are different products. Vaccines comprising an adjuvant and an antigen; adjuvants comprising either anti-CD28 antibody, B7.1 or B7.2; DNA encoding an antigen; DNA encoding an adjuvant as it reads on either anti-CD28 antibody, B7.1 or B7.2 or DNA encoding both an antigen and an antigen are distinct because their structures and modes of action are different, which require non-coextensive searches. Proteins or nucleic acids encoding anti-CD28 antibody, B7.1 or B7.2 encompass distinct structures and modes of action to such an extent that they are considered separately patentable. The recited products do not share substantial structural features essential to a common utility. Therefore, they are patentably distinct.

5. Inventions IV/V/VI and I/II/III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant, the vaccines can be made by a variety of recombinant and biochemical means, which do not rely upon the methods of Groups IV/V/VI.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XIX is not required for any other group from Groups I-XIX and Groups I-XIX have acquired a separate status in the art as shown by the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

8. In addition to electing a Group from above; this application contains claims directed to the following patentably distinct species of the claimed Groups I-IX:

A) wherein the antigen and adjuvant are cross-linked or
B) wherein the antigen and adjuvant are not physically co-joined.

These species are distinct because their structures differ and the methods rely upon different ingredients, process steps and endpoints. Therefore they are patentably distinct species

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
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September 30, 2004